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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/870,012	05/29/2001	Chaitan Khosla	300622000212	9415

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EXAMINER

KERR, KATHLEEN M

ART UNIT PAPER NUMBER

1652

DATE MAILED: 04/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/870,012

Applicant(s)

KHOSLA ET AL.

Examiner

Kathleen M. Kerr

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 February 2005.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19 and 24-26 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 19 and 24-26 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 11/4/04, 2/1/05.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Application Status

1. In response to the previous Office action, a non-final rejection (mailed on October 25, 2004), Applicants filed a response and amendment received on January 28, 2005. Said amendment amended Claims 19 and 24 and added new Claims 25-26. Thus, Claims 19 and 24-26 are pending in the instant Office action and will be examined herein.

Priority

2. As previously noted, the instant application is granted the benefit of priority for the U.S. Provisional Application No. 60/003,338 filed on July 6, 1995 and the U.S. non-Provisional Application No. 08/675,817 (now USPN 6,080,555) filed on July 5, 1996. Neither of these applications, however, disclosed the claimed invention of Claims 19 and 24.

The instant application is granted the benefit of priority for the U.S. non-Provisional Application No. 08/896,323 (USPN 6,066,721) filed on July 17, 1997 and the U.S. non-Provisional Application No. 08/434,289 (now USPN 6,261,816) filed on November 5, 1999. These applications do disclose the claimed invention. Thus, the earliest effective filing date of the claimed invention is considered to be July 17, 1997.

Information Disclosure Statement

3. The information disclosure statements filed on November 4, 2004 and February 1, 2005 have been reviewed, and their references have been considered as shown by the Examiner's initials next to each citation on the attached copies.

Art Unit: 1652

Withdrawn - Claim Objections

4. Previous objection to Claim 19 for a misspelling is withdrawn by virtue of Applicant's amendment.

5. Previous objection to Claim 24 for improper grammar is withdrawn by virtue of Applicant's amendment.

Withdrawn - Claim Rejections - 35 U.S.C. § 112

6. Previous rejection of Claims 19 and 24 under 35 U.S.C. § 112, second paragraph, as being indefinite is withdrawn. While the phrase "a modified 6-dEB" is somewhat confusing since 6-dEB is a single compound (RN 15797-36-2) and the article "a" indicates a set of compounds, it seems clear that Applicant intends to claim making all 6-dEB-like compounds wherein position 13 is modified.

Maintained - Claim Rejections - 35 U.S.C. § 112

7. Previous rejection of Claims 19 and 24 under 35 U.S.C. § 112, first paragraph, new matter, is maintained; new Claims 25-26 are added herein. Applicant's arguments have been fully considered but are not deemed persuasive for the following reasons.

Applicant argues that the Examiner indicates that the lack of a positive result being explicitly stated as the reason the genus of substituents at position 13 is not supported. While mention of this lack of explicitly stated generic conclusion is noted, the rejection was maintained because no support for the claimed genus is found in the specification as originally filed. As noted in the previous Office action as reiterated from previous Office actions,

Art Unit: 1652

“the instant claims gather their support *only* from Example 4 as originally filed; the remainder of the specification teaches invention(s) wholly distinct from the invention of Example 4, in particular using modified PKS genes (no modification of genes is found in the instant claims or in Example 4). Generic mention of “unnatural substrates” being accepted by post-PKS enzymes is noted on page 8, line 5; this reference does not support the genus because modified 6-dEB compounds are not particularly described [and because the genus of post-PKS enzymes, as a whole, is not a part of Example 4 or Claim 19]. Generic mention of “glycosylations at C3 and C5” are also noted at line 7; this reference also does not support the genus because modified 6-dEB compounds are not particularly described nor are non-native compounds whatsoever.

Experimentally in Example 4, mutant *S. erythraea* A34 is fed 6-dEB (compound 1) and makes an unnamed antibiotic (presumably compound 9 on Figure 3), and A34 is then fed compounds 6 and 7 and produces compounds 10 and 11, respectively, as evidenced after extraction. While this experiment supports the conclusion that *S. erythraea* may be able to glycosylate various derivatives of 6-dEB, such a conclusion is never stated.

There is no support in Example 4 for the following concepts (breadth) found in the claims:

- a) using *any* modified 6-dEB in the “adding” step - only adding compounds 1, 6, and 7 are supported, and
- b) using any *S. erythraea*, only the A34 strain is supported.” (emphasis in original)

As previously noted, it is the clear lack of discussion of Example 4 which limits the envisioned scope of the claimed invention. This is contrary to Applicant’s statement that “since ... the example is successful, it is clear that applicants contemplated generically the ability of the post-PKS enzymes to accept 6-dEB derivatives with alterations at position 13. The example specifies glycosylation as at least one of these post-PKS results. Accordingly, even if one accepts that the only support for claim 19 resides in Example 4, it is clear from the wording of this example itself that the scope of claim 19 as it pertains to the nature of the macrolide to be glycosylated is appropriate.” While Applicant may have envisioned more breadth than explicitly stated in Example 4, the fact that it worked does not support the implication of broader examples and, more importantly, does not support the particular genus of broader examples claimed.

Art Unit: 1652

Applicant also argues the holding that cells other than the A34 strain are not supported. “With respect to the assertion that the claims must be limited to a particular strain, A34, respectfully, it is believed that the Office has not met its burden to demonstrate why one would expect alternative *S. erythraea* strains to be inoperable.” Firstly, the Examiner never states that such methods would be inoperable. Secondly, operability is not at issue in this new matter rejection - support in the specification as originally filed is at issue and it has not been shown for reasons of record. Applicant again cites the generic language of page 8 of the originally filed specification; this disclosure cannot be linked to Example 4 wherein exclusive support for the instant claims is found.

Summary of Pending Issues

8. The following is a summary of the issues pending in the instant application:
 - a) Claims 19 and 24-26 stand rejected under 35 U.S.C. § 112, first paragraph, new matter.

Conclusion

9. Claims 19 and 24-26 are not allowed for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

Art Unit: 1652

MONTHS of the mailing date, of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M. Kerr whose telephone number is (571) 272-0931. The examiner can normally be reached on Monday through Friday, from 9:00am to 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kathleen M Kerr
Primary Examiner
Art Unit 1652

April 13, 2005